
- v. -

Defendants.

[illegible]

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TABLE OF CONTENTS

PRELIMINARY STATEMENT	1
BACKGROUND	1
I. Allegations of Misbranding and/or Adulteration With Intent to Defraud or Mislead.....	2
II. Allegations Regarding Michael Tannuzzo	6
ARGUMENT	6
I. APPLICABLE LAW	6
II. DISCUSSION	9
a. The Indictment States a Federal Offense in Language Tracking the Relevant Statutes	9
b. Section 333(a)(2) Unambiguously Prohibits Violations of the Federal Misbranding Laws Committed with an Intent to Defraud or Mislead, Without Further Limitation	10
c. Defendants’ Selective Citation to Past Cases Does Not Create an Ambiguity	12
d. Application of § 333(a)(2) to a Case in which an Offense is Committed With Intent to Defraud and Mislead a State Racing Commission or Track Officials Comes as No Surprise to the Defendants	24
e. Recent Passage of the Horseracing Integrity and Safety Act Has No Bearing on the Plain Language of § 333(a)(2)	27
f. Even on the Defendants’ Flawed Premise, the Indictment States an Offense	30
g. Tannuzzo’s Motion to Dismiss Should Be Denied	41
CONCLUSION.....	47

TABLE OF AUTHORITIES

Supreme Court Opinions

<i>Ali v. Fed. Bureau of Prisons,</i> 552 U.S. 214 (2008)	9
<i>Bostock v. Clayton Cty., Georgia,</i> 140 S.Ct. 1731 (2020)	28
<i>Boyce Motor Lines v. United States,</i> 342 U.S. 337 (1952)	7
<i>Braverman v. United States,</i> 317 U.S. 49 (1942)	44
<i>Chapman v. United States,</i> 500 U.S. 453 (1991)	25
<i>FDA v. Brown & Williamson Tobacco Corp.,</i> 529 U.S. 120 (2000)	28
<i>Food Marketing Institute v. Argus Leader Media,</i> 139 S.Ct. 2356 (2019)	12
<i>Hamling v. United States,</i> 418 U.S. 87 (1974)	41
<i>Hoffman Estates v. The Flipside, Hoffman Estates, Inc.,</i> 455 U.S. 489 (1982)	25
<i>Lamie v. U.S. Trustee,</i> 540 U.S. 526 (2004)	8
<i>Muscarello v. United States,</i> 524 U.S. 125 (1998)	9
<i>Parker v. Levy,</i> 417 U.S. 733 (1974)	24-25
<i>Republic of Iraq v. Beaty,</i> 556 U.S. 848 (2009)	28
<i>Sullivan v. Finkelstein,</i> 496 U.S. 617 (1990)	27

<i>United States v. Dotterweich</i> , 320 U.S. 277 (1943)	12
<i>United States v. Fausto</i> , 484 U.S. 439 (1988)	28
<i>United States v. Shabani</i> , 513 U.S. 10 (1994)	8
<i>United States v. United Mine Workers of Am.</i> , 330 U.S. 258 (1947)	27
Federal Court Opinions	
<i>Betancourt v. Bloomberg</i> , 448 F.3d 547 (2d Cir. 2006)	25
<i>United States v. Dessart</i> , 823 F.3d 395 (7th Cir. 2016)	18
<i>Buck v. Sec’y of Health & Human Servs.</i> , 923 F.2d 1200 (6th Cir. 1991)	28
<i>Farrell v. Burke</i> , 449 F.3d 470 (2d Cir. 2006)	24
<i>United States v. Industrial Laboratories Co.</i> , 456 F.2d 908 (10th Cir. 1972)	14, 15
<i>Lurie v. Wittner</i> , 228 F.3d 113 (2d Cir. 2000)	8
<i>United States v. DiCristina</i> , 726 F.3d 92 (2d Cir. 2013)	8
<i>United States v. Aleynikov</i> , 676 F.3d 71 (2d Cir. 2012)	7
<i>United States v. Alfonso</i> , 143 F.3d 772 (2d Cir. 1998)	7, 10
<i>United States v. Andersen</i> , 45 F.3d 217 (7th Cir. 1995)	18
<i>United States v. Arlen</i> , 947 F.2d 139 (5th Cir. 1991)	10-11, 20, 22

<i>United States v. Ballistrea</i> , 101 F.3d 827 (2d Cir. 1996)	20, 21
<i>United States v. Beech-Nut Nutrition Corp.</i> , 659 F.2d 1487 (E.D.N.Y. 1987)	15-16
<i>United States v. Bortnick</i> , No. 03 Cr. 414 (JD), 2005 WL 1693924 (E.D. Pa. July 20, 2005)	43
<i>United States v. Bout</i> , 731 F.3d 233 (2d Cir. 2013)	42, 43
<i>United States v. Bradshaw</i> , 840 F.2d 871 (11th Cir. 1988)	17, 18
<i>United States v. Cephas</i> , 937 F.2d 816 (2d Cir. 1991)	43
<i>United States v. Ellis</i> , 326 F.3d 550 (4th Cir. 2003)	18
<i>United States v. Genovese</i> , 409 F. Supp. 2d 253 (S.D.N.Y. 2005)	25
<i>United States v. Goldberg</i> , 756 F.2d 949 (2d Cir. 1985)	8, 9, 12
<i>United States v. Grissom</i> , 645 F.2d 461 (5th Cir. 1981)	22, 23
<i>United States v. Guttenberg</i> , No. 07 Cr. 141 (DAB), 2007 WL 4115810 (S.D.N.Y. 2007)	43
<i>United States v. Haga</i> , 821 F.2d 1036 (5th Cir. 1987)	19, 20
<i>United States v. Hebert</i> , 762 Fed. App'x 182 (5th Cir. 2019)	25, 26
<i>United States v. Levy</i> , No. S5 11 Cr. 62 (PAC), 2013 WL 664712 (S.D.N.Y. Feb. 25, 2013)	43
<i>United States v. Litchfield</i> , 986 F.2d 21 (2d Cir. 1993)	9, 11-12
<i>United States v. Litvak</i> , 2013 WL 5740891 (D.Conn. Oct. 21, 2013)	7

<i>United States v. McSherry</i> , 229 F.3d 1136 (2d Cir. 2000)	41-42
<i>United States v. Milstein</i> , 401 F.3d 53 (2d Cir. 2005)	13, 14, 16, 17, 20
<i>United States v. Mitcheltree</i> , 940 F.2d 1329 (10th Cir. 1991)	19, 32, 40
<i>United States v. Mitlof</i> , 165 F. Supp. 2d 558	43
<i>United States v. Montour</i> , 944 F.2d 1019 (2d Cir. 1991)	44
<i>United States v. Orrego-Martinez</i> , 575 F.3d 1 (1st Cir. 2009)	12
<i>United States v. Patwardhan</i> , No. 08 Cr. 172 (VAP), 2009 WL 2190191 (C.D. Cal. July 18, 2009)	13
<i>United States v. Persico</i> , 621 F. Supp. 842 (S.D.N.Y. 1985)	43
<i>United States v. Rojas</i> , --Fed. App'x --, 2021 WL 81698 (3d Cir. Jan. 11, 2021).	26
<i>United States v. Scully</i> , 170 F. Supp. 3d 439 (E.D.N.Y. 2016)	13
<i>United States v. Strauss</i> , 999 F.2d 692 (2d Cir. 1993)	24
<i>United States v. Stringer</i> , 730 F.3d 120 (2d Cir. 2013)	7
<i>United States v. Torres</i> , 901 F.2d 205 (2d Cir. 1990)	43
<i>United States v. Varela-Cruz</i> , 66 F. Supp. 2d 274 (D.P.R. 1999)	23
<i>United States v. Vitek Supply Corp.</i> , 144 F.3d 476 (7th Cir. 1998)	13
<i>United States v. Walsh</i> , 194 F.3d 37 (2d Cir. 1999)	7

United States v. Yannotti,

541 F.3d 112 (2d Cir. 2008) 6, 7

State Statutes

3 Del. Admin Code § 501	39
3 Del. Admin Code § 501-8.1	39
3 Del. Admin Code § 501-8.7.1.2	39
3 Del. Admin. Code. § 1001.15.1.1	40
3 Del. Admin. Code. § 1001.15.12.1	40
9 NYCRR § 4002.9	33
9 NYCRR § 4012.1	34
9 NYCRR § 4012.3	34
9 NYCRR § 4042.5	34
9 NYCRR § 4043.2	35
9 NYCRR § 4043.12	35
9 NYCRR § 4043.16	35
9 NYCRR § 4120.2	33
9 NYCRR § 4120.6	33
58 Pa. Admin. Code § 163.302	37
58 Pa. Admin. Code § 163.304	38
58 Pa. Admin. Code § 163.317	38
Fla. Stat. § 550.2415	36
Fla. Admin. Code § 61D-6.001	36
Fla. Admin. Code § 61D-6.003	36
Fla. Admin. Code § 61D-6.004	36
Fla. Admin. Code § 61D-6.008	37
Fla. Admin. Code § 61D-6.011	37
N.J. Admin. Code § 13:70-14A.1	38
N.J. Admin. Code § 13:70-27.2	39

PRELIMINARY STATEMENT

Certain defendants move to dismiss the operative indictment in this case on various grounds. Defendants Seth Fishman, Lisa Giannelli, Jordan Fishman, Rick Dane, Jr., Christopher Oakes, Jorge Navarro, and Erica Garcia each ask that this Court insert novel, unsupported, and self-serving language into the text of 21 U.S.C. § 333(a)(2) in an effort to avoid felony liability for their illegal misbranding conspiracies. (ECF Nos. 327 (“Fishman Motion” or “Fishman Mot.”), 328 (“Oakes Motion” or “Oakes Mot.”), 329-332). These motions contest only whether the Indictment properly charges them with intent to defraud or mislead as to particular classes of victims named in the Indictment. The motions do not contest either the underlying misdemeanor misbranding charge, or that at least one alleged victim, the Food and Drug Administration (“FDA”), is a cognizable victim under § 333(a)(2). These motions, therefore, do not actually seek the dismissal of the Indictment, but are more accurately described as premature motions regarding the sufficiency of the Government’s evidence to be presented at trial. In any event, the motions are also meritless as to the proposed limitation on cognizable victims.

Michael Tannuzzo also moves for dismissal of the indictment and explicitly, though prematurely, for a judgment of acquittal under Rule 29 of the Federal Rules of Criminal Procedure. (ECF No. 325). Tannuzzo’s motion is based largely on arguments regarding the sufficiency of the Government’s evidence, rather than on the text of the operative indictment. For the reasons set forth below, this motions, too, is without merit.

BACKGROUND

As alleged in the operative S6 Indictment, this case relates to overlapping and widespread schemes by racehorse trainers, veterinarians, drug distributors, and others to create, manufacture, distribute, and receive adulterated and misbranded drugs, and to administer those drugs to

racehorses in order to improve their race performance. These defendants and their coconspirators were driven by the desire to collect prize money from racetracks, all while avoiding detection and interdiction of their offense by various federal and state authorities, racetrack officials, owners, competitors, and others.

On or about February 26, 2020, a grand jury returned the superseding S6 indictment (the “Indictment” or the “S6 Indictment”). As relevant here: Navarro was charged in Counts One and Three of the Indictment with conspiring to violate the drug adulteration and misbranding laws, in violation of 18 U.S.C. § 371 and 21 U.S.C. §§ 331 and 333; Garcia, Tannuzzo, and Oakes were charged in Count One of the Indictment only; Seth Fishman was charged in Counts One and Two of the Indictment with violations of those same statutes; and Giannelli, Dane, and Jordan Fishman were charged in Count Two of the Indictment only.

The Government’s response to Seth Fishman’s Motion for a Bill of Particulars and to Dismiss the Indictment (ECF No. 210), sets forth many of the details of the case. In this filing, the Government focuses on two aspects of the S6 Indictment and, where relevant, pertinent evidence previously produced to the defendants. First, this section will note the allegations regarding misled and defrauded parties as set forth on the face of the Indictment, including entities such as the FDA, which even under the movants’ incorrectly narrow view of § 333(a)(2) would be a properly alleged victim. Second, this section will discuss the allegations against Michael Tannuzzo.

I. Allegations of Misbranding and/or Adulteration With Intent to Defraud or Mislead

The Indictment charges Seth Fishman, Christopher Oakes, Erica Garcia, and Michael Tannuzzo, among others, with participating in the horse doping operations centered around Jorge Navarro and his associates. For his part in this conspiracy, Seth Fishman (“Fishman”) created, manufactured, shipped and distributed misbranded and adulterated performance enhancing drugs

(“PEDs”) to Navarro and to Oakes (who, in turn, was a distributor of drugs to Navarro), and did so “with the intent to defraud or mislead” various actors described below. 21 U.S.C. § 333(a)(2). Oakes, a horse trainer, but also the distributor of illegally manufactured adulterated and misbranded drugs, assisted the Navarro conspiracy by, among other things, surreptitiously transporting misbranded and/or adulterated drugs into a racetrack at Navarro’s behest and for Navarro’s benefit. *See* Indictment ¶¶ 7, 18, 20(b)-(d), 29. Garcia provided and administered misbranded and adulterated PEDs to horses under Navarro’s control. Garcia did so at Navarro’s direction and without concern either for the composition of the substances she administered, or for any actual medical need for such substances by the affected horses. *See id.* ¶¶ 6, 29(d) (referring to the misbranded and adulterated blood builder drug “monkey”). Tannuzzo, for his part, assisted in the shipment, receipt, and delivery of misbranded and adulterated drugs at Navarro’s behest, as described in more detail below. *Id.* ¶¶ 16, 29(g).

Navarro is also charged in Count Three of the Indictment, relating to his role in assisting the misbranding and adulteration scheme centered around the doping operation of another trainer, Jason Servis, and his coconspirators. In the context of Count Three, Navarro is also alleged to have, among other things, shipped misbranded and adulterated drugs in interstate commerce, *id.* ¶ 40, and to have coordinated with Servis regarding the procurement, administration, and effective use of misbranded and adulterated drugs. *See id.* ¶¶ 40-42, 45, 52(a).

Fishman is further charged, along with Jordan Fishman, Giannelli and Dane, in a conspiracy centered around Fishman and his illegal drug manufacturing business (Count Two). As alleged, Fishman, together with Jordan Fishman, developed and produced an array of misbranded and adulterated drugs for use in doping racehorses. *See, e.g., id.* ¶¶ 8, 33. Giannelli operated as a distributor of Fishman’s products, and received products from Jordan Fishman for retail sales in

and around New York State; similarly, Dane acted both as a recipient of Fishman’s misbranded and adulterated products, as well as a distributor of the same. *See id.* ¶¶ 8, 33.

As relevant to the moving parties, the following allegations, among others, pertain to the nature of the conspiracies’ efforts to mislead and defraud others in order to accomplish the goals of the misbranding and adulteration schemes:

- “By evading PED prohibitions and *deceiving regulators and horse racing authorities, among others*, participants sought to improve race performance, increase a horse’s frequency of competition, and *obtain prize money from racetracks* throughout the United States and other countries, including in New York, New Jersey, Florida, Ohio, Kentucky, and the United Arab Emirates (“UAE”)” Indictment ¶ 2 (emphasis added); *see also id.* ¶¶ 15 (incorporating Paragraphs 1 through 8, and 11 through 14, into Count One), 30 (incorporating Paragraphs 1 through 4, 6, 8, and 11 through 14, into Count Two), and 39 (incorporating Paragraphs 1 through 4, 9, and 11 through 14, into Count Three).
- “[T]he scheme participants routinely defrauded and misled *government agencies, including federal and state drug regulators, U.S. Customs and Border Protection, various state horse racing regulators, certain horse owners, and the betting public.*” *Id.* ¶ 3 (emphasis added); *see also id.* ¶¶ 15, 30, 39.
- “[T]he defendants relied, in part, on their distribution and administration of customized PEDs designed and intended to be difficult or impossible to detect in anti-PED tests performed by, *among others, state racing regulators, by creating fraudulent or misleading labels for those PEDs, and by falsifying bills and*

invoices to conceal the use of certain drugs on affected horses.” Id. ¶ 3 (emphasis added); see also id. ¶¶ 15, 30, 39.

- “NAVARRO and his co-conspirators concealed the purchase and administration of adulterated and misbranded PEDs *from federal and state government agencies, racing officials, the betting public, and others.*” *Id. ¶ 5 (emphasis added); see also id. ¶¶ 15, 39.*
- “[SETH] FISHMAN and his co-conspirators further concealed the true nature and purpose of those adulterated and misbranded PEDs in order to defraud and mislead, among others, *federal and state government agencies and regulators.*” *Id. ¶ 8; see also id. ¶¶ 15, 30.*
- “OAKES confirmed that he would smuggle that PED into the racetrack and meet NAVARRO once inside.” “NAVARRO instructed OAKES to visit XY Jet to administer the PED, and *to lie to racing officials if necessary to access the racehorse:* ‘Drive through. If anything, if they stop you. You are an owner and you come to Navarro’s barn.’” *Id. ¶ 20(c)-(d).*

In sum, the Indictment expressly names federal, as well as state, government agencies, including both drug regulators and racing authorities, among the agencies that the defendants intended to mislead and defraud. Additionally, in order to accomplish the ends of the charged misbranding and adulteration conspiracy, U.S. Customs and Border Protection (“CBP”), racetrack officials, horse owners, and the betting public were all individuals or entities that the conspirators were obliged to mislead and defraud in the course of, and to accomplish the goals of, the charged conspiracies.

II. Allegations Regarding Michael Tannuzzo

Count One also charges Tannuzzo with participating in the Navarro Conspiracy. Tannuzzo was part of a group who “engaged in a corrupt scheme to manufacture, create, purchase, distribute, transport, sell, and administer a wide variety of misbranded and adulterated PEDs, as well as substances designed to mask the presence of PEDs from drug testing by racing and state officials,” Indictment ¶ 16, including by assisting Navarro in “obtaining, shipping, and administering misbranded and adulterated PEDs for NAVARRO’s benefit,” *id.* ¶ 7. Tannuzzo is specifically charged with having coordinated with Navarro to accept “a package of blood builder PEDs at Navarro’s New Jersey residence, which Tannuzzo in fact received on Navarro’s behalf.” *Id.* ¶ 29.g. Additional details regarding Tannuzzo’s participation in this scheme, pulled from evidence produced to Tannuzzo to date, are recounted below in response to Tannuzzo’s arguments regarding the purportedly innocent nature of his conduct. Count One also enumerates the statutory allegations against Tannuzzo and his coconspirators, tracking the applicable statutory text.

ARGUMENT

I. APPLICABLE LAW

a. Motion to Dismiss an Indictment

A defendant may move to dismiss an indictment on the grounds that it “fails to invoke the court’s jurisdiction or to state an offense.” Fed. R. Crim. P. 12(b)(3)(B). “An indictment is sufficient when it charges a crime with sufficient precision to inform the defendant of the charges he must meet and with enough detail that he may plead double jeopardy in a future prosecution based on the same set of events.” *United States v. Yannotti*, 541 F.3d 112, 127 (2d Cir. 2008) (quoting *United States v. Stavroulakis*, 952 F.2d 686, 693 (2d Cir. 1992)). Moreover, “an indictment need do little more than to track the language of the statute charged and state the time

and place (in approximate terms) of the alleged crime.” *Id.* (quoting *United States v. Alfonso*, 143 F.3d 772, 776 (2d Cir. 1998)). “An indictment need not be perfect, and common sense and reason are more important than technicalities.” *United States v. Stringer*, 730 F.3d 120, 124 (2d Cir. 2013) (internal quotation marks omitted).

The Second Circuit makes clear that a challenge to whether a statutory element has been satisfied is a matter for trial. *See Alfonso*, 143 F.3d at 776 (holding that an effect on interstate commerce was “itself an element of the offense charged” and “the determination of whether the jurisdictional element has been satisfied is part and parcel of the inquiry into the ‘general issue’ of whether the statute has been violated.”). In the context of a motion to dismiss the indictment, the Court must consider only the facts alleged in the indictment, and must “draw [] all favorable factual inferences for the government.” *United States v. Walsh*, 194 F.3d 37, 49 (2d Cir. 1999). In ruling on a motion to dismiss, a court views the indictment as a whole and assumes its factual allegations to be true. *Boyce Motor Lines v. United States*, 342 U.S. 337, 343 n.16 (1952). However, “[a] charge in an indictment is insufficient and must be dismissed when it does not describe conduct that is a violation of the criminal statute charged.” *United States v. Litvak*, 2013 WL 5740891, at *2 (D.Conn. Oct. 21, 2013) (citing *Russell v. United States*, 369 U.S. 749, 764-65 (1962); *United States v. Pirro*, 212 F.3d 86, 93 (2d Cir. 2000)); *see also United States v. Aleynikov*, 676 F.3d 71, 75-76 (2d Cir. 2012) (“Since federal crimes are solely creatures of statute, a federal indictment can be challenged on the ground that it fails to allege a crime within the terms of the applicable statute.” (citations and internal quotation marks omitted)).

b. Non-Applicability of the Rule of Lenity

Seth Fishman and Lisa Giannelli, on the one hand, and Christopher Oakes, on the other, have raised as a basis for dismissal the notion that the provision of 21 U.S.C. § 333(a)(2) making

their alleged conduct a felony—namely that their misbranding offense was “commit[ted] . . . with the intent to defraud or mislead”—is “ambiguous.”¹ On the basis of this purported ambiguity, they ask the Court to exercise the rule of lenity by inserting into § 333(a) several phrases (themselves undefined in the movants’ briefing) that neither appear in the text of the statute, nor comport with the broad protections of the FDCA. As discussed below, the motion to dismiss in light of that contention is meritless.

“The rule of lenity is a canon of statutory construction,” *Lurie v. Wittner*, 228 F.3d 113, 126 (2d Cir. 2000), “appl[ying] only when, after consulting traditional canons of statutory construction, [courts] are left with an ambiguous statute,” *United States v. Shabani*, 513 U.S. 10, 17 (1994). “It is well established that when the statute’s language is plain, the sole function of the courts—at least where the disposition required by the text is not absurd—is to enforce it according to its terms.” *Lamie v. U.S. Trustee*, 540 U.S. 526, 534 (2004) (internal quotation marks omitted). A statute is not “‘ambiguous’ for purposes of lenity merely because it [i]s possible to articulate a construction more narrow than that urged by the Government.” *United States v. DiCristina*, 726 F.3d 92, 104-05 (2d Cir. 2013) (quoting *Moskal v. United States*, 498 U.S. 103, 108 (1990) (emphasis in original)). Nor may a defendant create an ambiguity merely by proposing the inclusion of terms into a statute that do not otherwise exist. *See DiCristina*, 726 F.3d at 101-05 (rejecting defendant’s invitation to insert a new element into a statute defining “illegal gambling business”). “The rule of lenity is used only to resolve an ambiguity, not to . . . beget one.” *United States v. Goldberg*, 756 F.2d 949, 956 (2d Cir. 1985). Thus, when the statutory and regulatory provisions “unambiguously cover” the defendant’s conduct, the “rule of lenity does not come into

¹ As noted above, Navarro has joined in that argument as applied to Counts One and Three, Jordan Fishman and Dane have joined in that argument as applied to Count Two only, and Garcia has joined in that argument as applied to Count One.

play.” *Id.*; see also *Muscarello v. United States*, 524 U.S. 125, 138-39 (1998) (“The simple existence of some statutory ambiguity . . . is not sufficient to warrant application of that rule, for most statutes are ambiguous to some degree.”).

Breadth is not a synonym for ambiguity, and a broad proscription of conduct is not the same as a lack of clarity in legislative drafting. Where no ambiguity exists in a statute, the mere fact that its sweep is broad does not create ambiguity or necessitate a narrowing construction. See *Ali v. Fed. Bureau of Prisons*, 552 U.S. 214, 227 (2008) (“In the end, we are unpersuaded by petitioner’s attempt to create ambiguity where the statute’s text and structure suggest none. Had Congress intended to limit [statutory exemption from general waiver of sovereign immunity codified at 28 U.S.C.] § 2680(c)’s reach as petitioner contends, it easily could have written ‘any other law enforcement officer *acting in a customs or excise capacity*.’ Instead, it used the unmodified, all-encompassing phrase ‘any other law enforcement officer.’”). In short, “[t]he rule of lenity is not used to narrow a statute that has an unambiguously broad thrust.” *United States v. Litchfield*, 986 F.2d 21, 22 (2d Cir. 1993) (Per Curiam).

II. DISCUSSION

a. The Indictment States a Federal Offense in Language Tracking the Relevant Statutes

Section 333(a)(2) reads, in relevant part: “if any person . . . commits [a violation of 21 U.S.C. § 331] with the intent to defraud or mislead, such person shall be [guilty of a felony].” Absent such an intent (or a prior conviction for either a misdemeanor or felony violation of § 331, not applicable to the defendants currently charged in this case), a defendant who violates § 331 is guilty of a misdemeanor. 21 U.S.C. § 333(a)(1). Nowhere in the language of § 331, § 333, or anywhere else in the FDCA, is the felony provision of § 333(a)(2) further modified to limit the *cognizable victims* of a defendant’s fraud, such that a defendant’s fraudulent intent must

specifically contemplate, or be directed at, particular persons or entities. Rather, the statute reads as quoted above, focused squarely on the defendant's intent, rather than the identity of the defendant's victim.

In this case, the counts charging Fishman, Giannelli, Oakes, Navarro, Dane, Garcia, and Jordan Fishman, as well as the remaining counts of the Indictment, "meet[] the[] basic pleading requirements by accurately stating the elements of the offense charged and the approximate time and place [of the charged conspiracies]." *Alfonso*, 143 F.3d at 776. Nevertheless, the main argument of the motions filed by Fishman, Giannelli, and Oakes² is that the language of § 333(a)(2), making it a felony to commit a misbranding or adulteration violation described in § 331, must be read to refer only to the commission of a violation of § 331 "with an intent to defraud or mislead" *and* that the intent to defraud or mislead be directed at a conveniently narrow set of regulators and participants in the drug market. The motions are without merit, first because the plain language of the statute refutes that reading and, in any event, because the Indictment's enumeration of federal and state government agencies (including drug regulators) as victims refers to classes of victims that even the movants concede fall under the ambit of the FDCA. *See* Indictment ¶¶ 3, 5, 15, 30, 39.

b. Section 333(a)(2) Unambiguously Prohibits Violations of the Federal Misbranding Laws Committed with an Intent to Defraud or Mislead, Without Further Limitation

Section 333(a)(2) is a robust statute, but not an ambiguous one. In every instance in which a defendant commits a violation of the misbranding and adulteration laws set forth in § 331, that offense is a felony if, in the commission of that offense, the defendant acts with an intent to defraud

² The Government addresses defendant Tannuzzo's motion, including its meritless arguments regarding the applicable charging language, below.

or mislead. *See United States v. Arlen*, 947 F.2d 139, 145 (5th Cir. 1991) (“The prosecution [in a felony misbranding case] must prove beyond a reasonable doubt that a defendant intended to defraud or mislead *someone*, but the indictment need not specify the intended victim; *the focus is on defendant’s intent, not the victim’s identity.*” (emphasis added)). The words of the statute plainly impose increased punishment on defendants who increase the dangerousness of an underlying misbranding or adulteration offense by working to prevent the detection of that offense, or detection of the dangerousness of their illegal products. The defendants point to no ambiguity in any of the words of the statute, whether in the context of this specific clause, the subprovision of § 333(a)(2), or in the context of the misbranding laws generally.

Rather, the defendants complain (incorrectly)³ that this case is a novel application of the misbranding statutes to a case in which certain of the agencies, entities, and individuals deceived through the defendants’ misbranding conspiracies included state racing regulators. Notably, the defendants appear to concede that the language of the statute permits that *some* state regulators are properly within the ambit of § 333(a)(2), but claim that only state “drug regulators” or perhaps those concerned with “consumer protection” fall within the scope of the statute. *See Infra* Argument, Section 2.f. Without a plausible basis, as described in more detail below, the defendants then *exclude* state horse racing commissions and regulators from that artificially narrow scope, erroneously claiming that such regulators are *not* drug regulators and have no involvement in consumer protection. This contrivance is irrelevant because the statute unambiguously proscribes commission of a violation of § 331(a)(2) if committed “*with an intent* to defraud or mislead,” rather than “with [certain] intent[s] to defraud or mislead” or “with an intent to defraud or mislead [human (but not animal) consumers of drugs and certain, but not all, authorities involved in the

³ *See infra* Argument, Section 2.d.

regulation of the administration of drugs].” See *Litchfield*, 986 F.2d at 22 (“The rule of lenity is not used to narrow a statute that has an unambiguously broad thrust.”); *Goldberg*, 756 F.2d at 956 (citing *United States v. Moore*, 423 U.S. 122, 145 (1975)) (same); cf *Food Marketing Institute v. Argus Leader Media*, 139 S.Ct. 2356 (2019) (rejecting effort to narrow FOIA disclosure exemption through the creation and insertion of a “phrase that does not appear in the statute”).⁴

c. Defendants’ Selective Citation to Past Cases Does Not Create an Ambiguity

In an effort to invent a statutory limitation where none exists, the defendants turn to a series of cases that have discussed various victims in the context of felony § 333(a)(2) charges. The effort is flawed for two reasons.

First, even were the plain language of the statute ambiguous (which it is not), the defendants neglect any substantive discussion of cases in which companies, entities, and agencies, *other than* human consumers, the FDA, or “state drug authorities” were recognized as victims under the plain language of the § 333(a)(2). For example, in *United States v. Orrego-Martinez*, 575 F.3d 1, 6 (1st Cir. 2009), the First Circuit recognized that government agencies, and

⁴ Fishman and Giannelli further argue that the plain text of the FDCA dictates that the “victim must be narrowly construed as the FDA” when it is not the consumer, on the basis of a portion of the FDCA which purportedly mandates “that the FDA (not some other agency) is required to provide actual notice to a possible violator of the FDCA prior to institution of criminal charges, [thus] it is indisputable that the FDA is the agency defrauded or misled by such violations.” (Fishman Mot. at 12-13). This reasoning is fundamentally flawed. First, as discussed herein, the plain language does *not* limit the class of victims to consumers and the FDA only; defendants appear to concede as much later in their motion. Second, the argument obviously proves too much – even the moving defendants recognize that “consumers” (at least, human consumers) are protected victims under § 333(a)(2), notwithstanding their exclusion from the provisions of the FDCA cited by Fishman and Giannelli. Third, it is also not the case that the FDA must provide prior notice before a violator may be prosecuted, undermining any reliance on this provision to restrict the class of victims contemplated under the FDCA. See *United States v. Dotterweich*, 320 U.S. 277, 278-79 (1943) (Defendant “invoked s 305 of the Act requiring the Administrator, before reporting a violation for prosecution by a United States Attorney, to give the suspect an ‘opportunity to present his views.’ We agree with the Circuit Court of Appeals that the giving of such an opportunity, which was not accorded to [the defendant], is not a prerequisite to prosecution.”).

specifically U.S. Customs authorities, may be the object of deceit in a felony misbranding charge. See Indictment ¶ 3 (listing U.S. Customs and Border Protection among the agencies misled and defrauded through the defendants' schemes); see also *United States v. Vitek Supply Corp.*, 144 F.3d 476, 480 (7th Cir. 1998) (affirming conviction of defendant who engaged in a conspiracy to distribute adulterated or misbranded animal drugs with the intent to defraud "Customs and the FDA"); *United States v. Patwardhan*, No. 08 Cr. 172 (VAP), 2009 WL 2190191, at *11 (C.D. Cal. July 18, 2009), *aff'd*, 422 F. App'x 614 (9th Cir. 2011) (upholding conviction of defendant who acted with intent to defraud and mislead, among others, customs inspectors).⁵

The Second Circuit has also approved of a felony misbranding charge predicated on the basis that *wholesale distributors* who had unwittingly purchased misbranded drugs were properly the subject of a defendant's intent to defraud under the FDCA. See *United States v. Milstein*, 401 F.3d 53, 69-70 (2d Cir. 2005). In *Milstein*, as in this case, a defendant attempted to gerrymander the scope of § 333(a)(2) so as to preclude "the purchasing public and government agencies" as intended objects of the charged offense, leaving as the only victim the wholesale distributors that had purchased Milstein's misbranded drugs. *Id.* at 69. The Circuit in *Milstein* rejected that effort, recognizing that not only "the wholesale distributors who made direct purchases from Milstein but also retail consumers and government agencies" were properly considered potential victims of the charged offense.⁶ Noting the "overriding congressional purpose" of the FDCA, *id.* at 69 (quoting

⁵ See also *United States v. Scully*, 170 F. Supp. 3d 439, 472 (E.D.N.Y. 2016), *vacated in part on the basis that court erroneously excluded advice-of-counsel defense*, 877 F.3d 464 (2d Cir. 2017) (District Court held that there was sufficient proof that defendants "knowingly engaged in illegal conduct designed to defraud customers, customs officials, and the FDA based on evidence demonstrating that defendants "engaged in elaborate importation techniques to ensure that packages of unapproved and misbranded drugs successfully entered the country without detection by investigators and customs officials.").

⁶ The Circuit in *Milstein* reversed the defendant's conviction on the relevant misbranding offenses, not due to any overbreadth in the proposed scope of § 333(a)(2), but on the basis of a constructive amendment to the indictment at the time of trial. Specifically, the Government proved at trial that Milstein's drugs were

United States v. Mitcheltree, 940 F.2d 1329, 1348 (10th Cir. 1991)), the Second Circuit made specific reference to the statutory text in rejecting Milstein’s attempt to insert an artificial limitation: “nothing in the language of the pedigree statute [21 U.S.C. § 353(e), a predicate for misbranding under § 331(t)] precludes the ‘intent to defraud’ provision [of 21 U.S.C. § 333(a)(2)] from applying to the purchasing public.” *Id.* The same is true in this case: nothing in the text of either § 331 or § 333(a)(2) precludes the “intent to defraud or mislead” provision from applying to any party whom the defendants intended to mislead in order to accomplish the object of their criminal activity, including state racing commissions dedicated to monitoring the administration of drugs to racehorses.⁷ The defendants in this case neglect to mention that *Milstein*’s victims included “wholesale distributors,” a category of victim that would, nonsensically, fall outside of the defendants’ baseless limitation. (See *Oakes Mot.* at 7 (referring only to the FDA); see also *Fishman Mot.* (no discussion of *Milstein*)).

Likewise, in *United States v. Industrial Laboratories Co.*, 456 F.2d 908 (10th Cir. 1972), the Tenth Circuit considered a case in which the defendants (a company and employee involved in the testing and analyses of food and drug products) devised reports falsely indicating that certain tests had been performed on particular products when, in fact, those tests had not been performed. The defendants’ tests and reports were intended for provision not to the FDA or any consumer, but

misbranded in part “because they were supposedly sterile when they were not,” whereas that particular basis for a finding that the drugs were misbranded was not included in the operative indictment. *Milstein*, 401 F.3d at 64.

⁷ The Second Circuit observed in *Milstein* that “[t]he very nature of the fraud as alleged in the indictment [against Milstein] implies an intent to defraud consumers,” even though Milstein did not sell to them directly, because the scheme “on its face [was] designed to deceive all purchasers in the chain of distribution,” *id.* at 70, and that “[b]y misleading governmental agencies, and thereby frustrating their efforts to protect the public, Milstein indirectly misled and defrauded the public.” *Id.* at 69 (internal quotations omitted). Likewise, state racing commissions are properly considered victims under the FDCA, as the defendants’ schemes angled to deceive those agencies and to defeat their efforts to protect the health and safety of animals competing in races under the oversight of those agencies.

to an intermediate drug company regulated by Canadian authorities. In reversing the defendants' convictions in light of deficient jury instructions, the Tenth Circuit noted: "The jury should have been further directed that it was necessary for it to find that the defendant knew that the several tests had not been made, that Ochs [an individual defendant] intentionally misrepresented that they had, and that he did so *for the purpose of misleading and defrauding the consignee and the Canadian authorities* that such several tests had in fact been performed." *Industrial Laboratories Co.*, 456 F.2d at 910-11 (emphasis added).

That an intermediate retailer, shipper, consignee, or drug compounder might properly be the object of a fraud under § 333(a)(2) is unsurprising in light of the plain language of the FDCA. For example, § 331 prohibits not only "[t]he introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded," and not only "[t]he adulteration or misbranding of any . . . drug . . . in interstate commerce," but "the *causing*" of those and other acts. Thus, an actor may well attempt to defraud or mislead a manufacturer, supplier, consignee, or other actor in an effort to cause the third party to engage in or overlook the misbranding or adulteration of a covered product, while still incurring felony criminal liability. Section 333(a)(2)'s focus on the defendants' intent, rather than on the particular victim of that intent, accounts for even those eventualities. *See, e.g., United States v. Beech-Nut Nutrition Corp.*, 659 F.2d 1487 (E.D.N.Y. 1987) (describing felony charges involving a two-stage fraud in the distribution (stage one, defrauding an intermediate distribution company) and then the sale to the public (stage two) of adulterated apple juice and apple juice concentrate); *aff'd in part and rev'd in part on other grounds by United States v. Beech-Nut Nutrition Corp.*, 871 F.2d 1181 (2d Cir. 1989) (upholding conviction of Beech-Nut employee despite co-conspirators also having defrauded Beech-Nut itself) ("Though Lavery asked the court to instruct the jury also that he could not be found guilty

of conspiring with the suppliers if the jury found that the suppliers sought to defraud Beech-Nut, the court's refusal to give that charge was not error, for the requested instruction does not accurately reflect the law.").

The defendants' invented restriction would exclude from felony liability any number of particularly egregious fraudulent schemes that take aim at pre-consumer levels of the drug supply and distribution chain, despite the plain language of § 333(a)(2), and that of § 331 proscribing intermediaries "causing" others to introduce misbranded or adulterated products into interstate commerce. For example, on the defendants' proposed amendment to § 333(a)(2), a pharmaceutical company sales representative who submits false prescriptions to cause his own company to supply illegal prescription drugs to a racehorse trainer at the trainer's behest, while directing his intent to mislead at his own employer in an effort to fraudulently boost his sales commission, and without contemplating the FDA, would not have committed a felony violation of the FDCA. On the defendants' proposed theory, an upstream supplier of component chemicals for use in the preparation of a drug by an intermediary drug company may—with impunity—lie to that intermediary company regarding the content and quality of its component chemicals without concern for a felony prosecution under the FDCA so long as they direct their intent toward the defrauded party and not toward the FDA or downstream consumers. The variations are endless, and each would allow for an actor who fraudulently "causes," anyone apart from a consumer to create or transport illegally misbranded or adulterated drugs to escape felony prosecution on the theory that the FDCA's criminal fraud proscription simply does not contemplate such liability. *See* 21 U.S.C. §§ 331, 333. That result is squarely at odds with the language of § 333(a)(2), the scope of § 331, the Second Circuit's opinion in *Milstein*, and with common sense.

Second, the defendants, in their selective marshalling of cases, fail to note that not a single case cited by the defendants purports to impose the limitation suggested by the defendants in their motions. Defendants request, rather, that this Court engage in a novel and unsupported alteration of the statutory text. As described below, the cases cited by the defendants in fact stand for the proposition that an intent to defraud or mislead must be held “with” (that is, in “connection to” or as the “manner of” the commission of) the underlying misbranding offense. These courts have consistently read § 333(a)(2) *expansively* so as to capture the charged object of various fraudulent schemes, and just as consistently have rejected various attempts to impose unfounded limits on the statute’s scope.

Milstein encapsulates the Second Circuit’s rejection of efforts to artificially cabin Section 333(a)(2). As discussed above, in a reversal of the defendants’ position here, the defendant in *Milstein* argued that the FDA and consumers were not proper victims of the FDCA, only the wholesale purchasers of the drug could be considered victims. 401 F.3d at 69-70. This specious reasoning was rejected, with the Second Circuit noting that there was no such limitation in the text of the statute. *Id.* at 69 (“[N]othing in the language of the pedigree statute precludes the ‘intent to defraud’ provision from applying to the purchasing public.”).⁸

Similarly, in *United States v. Bradshaw*, 840 F.2d 871 (11th Cir. 1988), the Eleventh Circuit confronted a defendant’s attempt to impose another self-serving limitation on the language of § 333(a)(2) (then codified as § 333(b)). In that case, Bradshaw urged the court “strictly to limit the

⁸ Below, the Government discusses the powers and duties of various racing commissions, including their express duties to safeguard the health and safety of performance animals. In the context of this discussion of *Milstein*, it bears noting that the “public” or the “consuming public” in the context of *animal* drugs is analogous to the animals into which misbranded or adulterated drugs may be injected or otherwise administered. Actors, such as intervening drug retailers, pharmacists, or state agencies dedicated to protecting those animals, are properly considered actors undertaking “efforts to protect the public,” in the words of *Milstein*. As discussed in more detail below, therefore, the defendants’ arguments collapse even under their own incorrect assumptions.

felony penalty to situations in which the conduct defrauds or misleads the ultimate consumer.” *Bradshaw*, 840 F.2d at 874. The *Bradshaw* court rejected that invitation. The court began, as was proper, with the statutory text: “We see no indication in the language of the statute or its legislative history that Congress meant to limit the felony penalty to conduct intended to defraud the ultimate consumer to the exclusion of the government enforcement agencies.” *Id.* Moreover, the *Bradshaw* court expressly held that the language of the statute, along with its apparent purpose, was “flexible enough to cover unforeseen situations,”⁹ even involving situations in which a defendant’s fraudulent intent in the course of a misbranding offense is directed at some novel class of victims. *Id.* at 875; *see also id.* (“We believe that had Congress intended to limit the intent requirement to an intent to defraud consumers, it would have plainly said so.”).¹⁰ The defendants’ error in reading *Bradshaw*, and the other cases discussed below, is their assumption that the Eleventh Circuit *limited* the class of victims contemplated by the FDCA. It did not. Indeed, no court has found that the FDCA extends to federal and state drug regulatory authorities and consumers, to the exclusion of all other contemplated victims. In finding that the FDCA extended to a particular class of victim

⁹ The *Bradshaw* Court further illustrated this point by citing a series of cases in which “[c]ourts . . . repeatedly interpreted analogous provisions [*i.e.*, provisions referring to a defendant’s intent to defraud] to include entities other than those one would normally expect to be the parties defrauded.” *Bradshaw*, 840 F.2d at 875.

¹⁰ Other cases cited by the defendants are similar in posture and result to those of *Bradshaw*. In *United States v. Dessart*, 823 F.3d 395, 403 (7th Cir. 2016), the Court found that “either consumers or the FDA or both” may be considered as victims for purposes of § 333(a)(2), in the context of a case in which the FDA was the sole agency proffered as a potential victim in the Government’s case. *See also* Rep. Br. of Appellant Dessart, *United States v. Dessart*, 2015 WL 2337523, at *9 (May 13, 2015). The same essential posture is true of *United States v. Andersen*, 45 F.3d 217 (7th Cir. 1995) (acknowledging that a regulatory agency, there the FDA, may be a victim for purposes of a similar anti-fraud provision of the relevant misbranding Sentencing Guideline); *United States v. Ellis*, 326 F.3d 550 (4th Cir. 2003) (rejecting a sufficiency of the evidence challenge in the context of a case involving proof that a defendant intended to defraud or mislead the FDA, in particular).

at issue, courts have not held—directly or by implication—that no other entity could properly be considered a victim.¹¹

A different posture underlies the decision in *United States v. Mitcheltree*. In *Mitcheltree*, the Tenth Circuit reversed misbranding felony convictions on the grounds that the Government had not provided sufficient evidence tying a misbranding offense to any intent to mislead or defraud – in effect, failing to present evidence that the misbranding offense was committed “with” an intent to defraud or mislead. 21 U.S.C. § 333(a)(2); *see also Mitcheltree*, 940 F.2d 1329, 1351 (10th Cir. 1991) (“The felony provision requires knowledge of the misbranding and proof of specific intent to mislead or defraud *connected to* the misbranding violation.” (emphasis added)).¹² The *Mitcheltree* court, weighing the sufficiency of the evidence proffered in the context of that case, used various phrasing to describe what would constitute a sufficient showing of intent: “The government may premise criminal liability under § 333(a)(2) based upon an intent to mislead or defraud not only natural persons, but also government agencies if there is evidence that a defendant consciously sought to mislead drug regulatory authorities such as the FDA or a similar governmental agency,” *id.* at 1347; “We do not read [*United States v. Haga*, 821 F.2d 1036 (5th

¹¹ Moreover, defendants point to *Bradshaw*’s discussion of certain provisions of § 331 (which are *not* charged in this matter) in which the violation makes it “clear that the FDA is the entity most likely to be defrauded under these provisions.” (Fishman Mot. at 12 (citing *Bradshaw*, 840 F.2d at 874-75)). The *Bradshaw* Court merely concluded that with respect to those provisions (*i.e.*, the failure to register with the FDA, failure to permit FDA access to records, failure to make reports to the FDA, and refusal to permit FDA inspection) the FDA was the “most likely victim”—but the *Bradshaw* Court did not conclude that the FDA was the *only possible* victim.

¹² Notably, and as argued in the Government’s opposition to Seth Fishman’s Motion for a Bill of Particulars and to Dismiss the Indictment, (ECF No. 210), the *Mitcheltree* Court was evaluating the sufficiency of the Government’s evidence *at trial* of the defendant’s intent to defraud or mislead local police departments that generally conducted “routine controlled substance investigations.” In other words, *Mitcheltree* did not reach the conclusion the defendants advocate here, which is that state agencies can *never* be the object of a defendant’s intent to defraud or mislead, only that there was insufficient proof at trial in that case that the defendants misbranded drugs “with the specific intent to defraud or mislead *those police departments*” that were the purported objects of deception. 940 F.2d at 1351 (emphasis added).

Cir. 1987)] as foreclosing a prosecution on the theory that *during the course* of misbranding drugs the FDA or its state counterpart has been misled or defrauded by a misrepresentation or omission,” *id.* at 1348 (emphasis added); “if the government proceeds on this theory, there must be a *demonstrated link between the § 331 violation* and an intent to mislead or defraud an identifiable drug regulatory agency involved in consumer protection,” *id.* at 1349 (emphasis added).¹³

Mitcheltree’s emphasis is on the language of § 333(a)(2): A violation of the misbranding laws committed “with” an intent to defraud or mislead is a felony offense, while a violation of those laws “with[out]” such an intent connected to the offense is a misdemeanor. *Mitcheltree* did not have cause to consider a case in which a misbranding offense might be committed “with” an intent to defraud or mislead a government agency *not* involved solely, or even primarily, in drug regulation. Nevertheless, the opinion indicates that a wide range of government agencies may well be tied, in any particular case, to such an intent: “What is missing in this case is (1) any conscious involvement by the defendant with a government agency involved in consumer protection which performs any of the above [referring to a non-exhaustive list including the inspection of drugs, regulations of “the use of” prescription drugs, and issuance of permits to drug wholesalers] *or similar* functions, and (2) any link between conscious misbranding activity and a specific intent to mislead or defraud such an agency.” *Id.* at 1352 (emphasis added).

As discussed in more detail below, state racing regulators certainly qualify as regulators overseeing “the use” of drugs, even assuming that *Mitcheltree* may be read (out of context) as

¹³ Defendants’ reliance on *Haga* for support is unfounded given that the Fifth Circuit in *Haga* only expressed its opinion in dicta and explicitly said it was not deciding the question of whether government agencies could be victims under the FDCA. *See Haga*, 821 F.2d at 1041. This restriction was rejected by the Second Circuit in *Milstein*; more to the point, upon revisiting this question, the Fifth Circuit in *Arlen* expressly disavowed the *Haga* Court’s commentary, holding that an FDCA felony violation could be predicated upon “the specific intent to defraud or mislead an identifiable government agency.” *See Arlen*, 947 F.2d at 143.

imposing limits on the identities of victims.¹⁴ Those involved in marketing, shipping, and administering misbranded drugs are, of course, unlikely to hold a specific intent to defraud or mislead an agency *not* involved in some capacity in the regulation or interdiction of misbranded or adulterated drugs. In this case, the defendants’ well-documented efforts to evade detection by state racing officials is itself evidence that such agencies *are* so involved. Nevertheless, a dealer in misbranded or adulterated drugs who devised a scheme to mislead and defraud a regulator far afield from the world of drug use and administration—for example, a securities regulator with oversight of a publicly traded pharmaceutical company—by lying to that securities regulator regarding that company’s drug manufacturing licensing status *in an effort to continue and conceal* its misbranding activities, would nonetheless be guilty of misbranding and adulterating drugs “with” an intent to defraud and mislead, exactly as the statute provides. *Mitcheltree* does not purport to address such a situation or to impose any limitation to the contrary.

Defendants each refer to *United States v. Ballistrea*, 101 F.3d 827 (2d Cir. 1996). The *dictum* in *Ballistrea* on which the defendants rely is simply inapposite to a motion to dismiss. *Ballistrea* noted that “[b]ecause the concept of ‘defrauding’ under 21 U.S.C. § 333(a)(2) has not been as broadly construed as its linguistically identical counterpart in 18 U.S.C. § 371, cases [involving § 333(a)(2)] requiring the Government to show actual contact between the defendant and a Government agency or its officials to sustain a conviction under the former provision are irrelevant to the present case [charged as a *Klein* conspiracy under § 371, without reference to an

¹⁴ Notably, the Second Circuit cases that have cited *Mitcheltree* have not found that its holding restricts felony FDCA violations to cases where defendants seek to defraud federal agencies only. *See, e.g., Milstein*, 401 F.3d at 69 (*Mitcheltree* “is persuasive, holding that a defendant may be convicted on evidence that *government agencies* were the subject of the intent to defraud.” (emphasis added)); *United States v. Ballistrea*, 101 F.3d 827, 833 (2d Cir. 1996) (citing *Mitcheltree* in support of principle that FDCA felony provision encompassed “an ‘intent to defraud or mislead’ either end users or Government agencies.”).

underlying criminal statute].” *Ballistrea*, 101 F.3d at 833. Whatever the proof required to demonstrate “actual contact” in a § 333(a)(2) charge (including proof of “active concealment,” *id.* at 833 n. 3), that is a question to be left for trial, rather than on a motion to dismiss the indictment as facially insufficient.¹⁵

Finally, the defendants’ reliance on *United States v. Grissom*, 645 F.2d 461 (5th Cir. 1981), is unavailing. The defendants cite *Grissom* for the proposition that the language of § 333(a)(2) must be ambiguous simply because it does not limit the class of victims who may be defrauded or misled in the course of a misbranding offense. (Oakes Mot. at 13; Fishman Mot. at 45). *Grissom* is inapposite in several respects. First, it is difficult to reconcile the implication that the defendants ascribe to *Grissom* in light of the subsequent Fifth Circuit opinion in *United States v. Arlen*, 947 F.2d at 145, in which the Fifth Circuit appropriately construed the plain language of the misbranding felony statute at issue in this case: “The prosecution [in a felony misbranding case] must prove beyond a reasonable doubt that a defendant intended to defraud or mislead *someone*, but the indictment need not specify the intended victim; *the focus is on defendant’s intent, not the victim’s identity*.” *Id.* (emphasis added)).¹⁶ *Id.* Thus, even the Fifth Circuit appears to ascribe no controlling significance to the *Grissom* court’s discussion of ambiguity in a separate context.

¹⁵ Without tendering a complete preview of the proof of “actual contact,” including “active concealment,” among the conspirators with respect to relevant agencies and other victims, the Government notes that ample proof of such contact and concealment exists as to each of Oakes, Fishman, and Giannelli, among others. *See, e.g.*, Indictment ¶¶ 20(d) (describing Oakes’ agreement with defendant Jorge Navarro to lie to racing officials who might attempt to interdict Oakes’ smuggling of a misbranded and adulterated drug on Navarro’s behalf); 38(c) (describing false statements provided to the Delaware Division of Professional Regulation regarding their joint distribution of misbranded and adulterated drugs).

¹⁶ In their brief, Fishman and Giannelli describe the holding of *Arlen* as “upholding conviction based on theory that defendant defrauded and or mislead *the FDA*.” (Fishman Mot. at 24 (emphasis in original)). The specific facts in *Arlen* centered on a claim that the FDA had been misled and defrauded, but that case cannot reasonably be read to imply, much less hold, that the FDA is the *sole* agency that may fall within § 333(a)(2)’s ambit, especially in light of the *Arlen* court’s express recognition that “the focus is on the defendant’s intent, not the victim’s identity.” 947 F.2d at 145. This misreading in Fishman and Giannelli’s treatment of *Arlen* is repeated in the defendants’ treatment of the case law, generally.

Second, *Grissom*'s ruling was made against the backdrop of what that court viewed as a potential for significantly altering the federal-state balance of regulation of local, private disputes among landlords and tenants. *Grissom*, 645 F.2d at 467 ("The second crucial and extremely relevant principle of statutory interpretation which mandates the reversal of *Grissom*'s conviction provides that unless Congress conveys its purpose clearly, it will not be deemed to have significantly changed the federal-state balance." (quotation marks omitted)); *id.* at 461 ("In our federalist system of government, pernicious conduct may be punishable under federal law, state law or both sets of laws simultaneously. The structure of our government imposes a duty upon the judiciary to decide not only whether a given course of conduct is illegal, but also, by which sovereign's commands such conduct has been outlawed.").

The *Grissom* court's federalism concern is entirely lacking in this case. The defendants in this case are not charged with violating state racing rules, as defendants wrongly imply in their motions. Rather, the defendants are charged with engaging in violations of the federal misbranding laws through the introduction, administration, shipment, receipt, purchase, and sale of misbranded and adulterated drugs in interstate commerce—conduct that squarely falls under the purview of federal authority. The defendants do not, and cannot seriously, suggest that this conduct, namely, the manufacture of adulterated and misbranded drugs shipped interstate, is not properly within the scope of federal proscription.¹⁷ Indeed, even absent proof of fraudulent intent, the defendants

¹⁷ The defendants in *United States v. Varela-Cruz*, 66 F. Supp. 2d 274, 281 (D.P.R. 1999), raised a similar argument as the defendants here, moving to dismiss an Indictment charging felony violations of the FDCA on the premise that there was insufficient federal criminal subject matter jurisdiction over the shipment of milk within Puerto Rico (and not interstate), a market that had regularly been regulated and overseen by state authorities. The District Court summarily dismissed that claim: "Defendants allege that the crime of milk adulteration in Puerto Rico is strictly state-oriented violation and, therefore, there is no federal jurisdiction. To support this contention, Defendants cite a litany of state cases dealing with adulterated milk. Nonetheless, this claim is patently incorrect. The charge against Defendants is for violation of federal laws, 21 U.S.C. §§ 331(a) and 333(a)(2) and 18 U.S.C. § 871. Therefore, federal criminal jurisdiction exists

would be liable for misdemeanor crimes under the FDCA for the interstate and international shipment of these illegal drugs. The egregiousness of the defendants' conduct is heightened because their offenses were committed "with the intent to defraud or mislead," and Congress chose to increase the punishment for this federal crime (from a misdemeanor to a felony) committed with such an intent. The heightened punishment, however, does nothing to expand the reach of § 331, or mean that these crimes fall out of the ambit of federal law. The intent requirement simply expands the penalties for the underlying offenses covered by § 331, all of which are properly within the scope of federal legislation, and have been for nearly a century.

In sum, the defendants' selected cases do not purport to establish the self-serving limitation on § 333(a)(2) that the defendants advocate. Nor do the cases suggest that the structure or purpose of the FDCA would exclude a particular class of person or agency from the ambit of § 333(a)(2) in a case in which misleading that victim is an integral part of achieving, continuing, or completing the underlying misbranding offense – that is, where the misbranding offense is committed *with* the intent to defraud and mislead.

d. Application of § 333(a)(2) to a Case in which an Offense is Committed With Intent to Defraud and Mislead a State Racing Commission or Track Officials Comes as No Surprise to the Defendants

Because the language of § 333(a)(2) is unambiguous, there is no merit to Fishman and Giannelli's purported claim of surprise that their conduct has resulted in federal charges.¹⁸ "[O]ne

by virtue of the charges coupled with the aforementioned interstate commerce element. The mere existence of state cases and parallel state statutes does not preclude federal jurisdiction in this case." *Id.* at 280. Similarly here, merely because state authorities have jurisdiction over racing violations, does not preclude or override federal jurisdiction over deceptive conduct linked to the interstate shipment and administration of adulterated and misbranded drugs.

¹⁸ "Courts have looked with disfavor on facial vagueness challenges to statutes that do not implicate fundamental rights." *Farrell v. Burke*, 449 F.3d 470, 495 (2d Cir. 2006). "Facial vagueness challenges may go forward only if the challenged regulation 'reaches a substantial amount of constitutionally protected conduct.'" *Id.* at 496 (quoting *Kolender v. Lawson*, 461 U.S. 352, 358 n.8 (1983) (internal citation and

whose conduct is clearly proscribed” by a law may not challenge the law on the ground of purported vagueness. *United States v. Strauss*, 999 F.2d 692 (2d Cir. 1993); *see also Parker v. Levy*, 417 U.S. 733, 756 (1974) (“One to whose conduct a statute clearly applies may not successfully challenge it for vagueness.”); *Hoffman Estates v. The Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 495 (1982) (“A plaintiff who engages in some conduct that is clearly proscribed cannot complain of the vagueness of the law as applied to the conduct of others.”). Further, “[s]ome inherent vagueness’ is inevitable and thus permissible” in statutes. *United States v. Genovese*, 409 F. Supp. 2d 253, 357 (S.D.N.Y. 2005) (quoting *Rose v. Locke*, 423 U.S. 48, 49-50 (1975) (void-for-vagueness doctrine “does not invalidate every statute which a reviewing court believes could have been drafted with greater precision”)). “Regulations need not . . . achieve ‘meticulous specificity,’ which would come at the cost of ‘flexibility and reasonable breadth.’” *Betancourt v. Bloomberg*, 448 F.3d 547, 552-53 (2d Cir. 2006) (citing *Grayned v. City of Rockford*, 408 U.S. 104, 110 (1972)).

Moreover, Fishman and Giannelli concede that the current case is *not* novel in its application of § 333(a)(2) to defendants whose misbranding offenses are motivated by a desire to make money specifically through doping racehorses. *See Chapman v. United States*, 500 U.S. 453, 467 (1991) (“[T]he vagueness claim must [instead] be evaluated as the [proscription] is applied to the facts of th[e] case [at hand].”).

The Fifth Circuit in *United States v. Hebert*, 762 Fed. App’x 182 (5th Cir. 2019) (non-precedential), specifically reviewed the district court’s jury instructions regarding willfulness in the context of a felony misbranding case regarding a veterinarian involved in creating, shipping,

quotation marks omitted)). The FDCA’s prohibitions against distributing interstate adulterated and misbranded drugs implicates no constitutional rights.

and distributing various misbranded drugs for the purpose of doping horses racing in Louisiana. Among other things, “Hebert [a veterinarian] assured trainers that these injections would not ‘test’ should the Racing Commission screen their horses for banned substances.” Br. of United States, *United States v. Hebert*, 2018 WL 3729461, at *3-*4 (Aug. 3, 2018) (citing record on appeal). The Fifth Circuit reviewed the case, including its jury instructions, in the context of a case involving a felony misbranding offense committed “with the intent to defraud federal and *state regulatory agencies* including the federal Food and Drug Administration.” *Hebert*, 762 Fed. App’x at 183 (emphasis added). The state regulatory agencies at issue in *Hebert* were the Louisiana Racing Commission and state police, in addition to the FDA.

Similarly, the Third Circuit recently affirmed the conviction of a racehorse trainer in *United States v. Rojas*, --Fed. App’x --, 2021 WL 81698 (3d Cir. Jan. 11, 2021). *Rojas* – who was indicted in or about 2015 – was convicted of felony misbranding based on her efforts to evade Pennsylvania racing regulations. In addressing *Rojas*’ contention that the Government presented no evidence that she “engaged in any fraud or attempted to cover up her activities,” the Third Circuit wrote:

Felony misbranding requires the Government to prove ‘intent to defraud or mislead.’ There was evidence presented at trial tending to show that *Rojas* knew of the falsified reports, instructed the veterinarians to inject substances within twenty-four hours of post time, thus necessitating the falsified reports, knew that administering drugs on race day violated Pennsylvania regulations, and knowingly participated in the entire venture. The veterinarians testified that they willingly participated in the scheme and understood that it was illegal. And the jury returned a special interrogatory in the verdict form finding that *Rojas* acted with the requisite intent to defraud or mislead. We see no error in the District Court’s sentencing *Rojas* for felony misbranding.

Rojas, 2021 WL 81698, at 6. Although Fishman and Giannelli emphasize that this was a ruling about the District Court’s decision “to sentence” *Rojas* under the misbranding felony provision of § 333(a)(2), *see* Fishman Mot. at 32, the decision in *Rojas* makes plain that this was not a ruling based on the language of the Sentencing Guidelines or on the general sentencing principles in 18

U.S.C. § 3553(a). Rather, as the Third Circuit stated, Rojas was properly subject to felony punishment under § 333(a)(2) because her conduct fell within the scope of that statute.¹⁹

e. Recent Passage of the Horseracing Integrity and Safety Act Has No Bearing on the Plain Language of § 333(a)(2)

The defendants’ respective discussions of the passage of what is commonly referred to as the Horseracing Integrity and Safety Act of 2020 (“HISA”)²⁰ in the Fishman Motion and the Oakes Motion shed no light on the purpose or application of the FDCA. (*See* Fishman Mot. at 41-42; Oakes Mot. at 15-16). That is because the 116th Congress’s passage of the HISA in 2020 has no bearing upon the intent of the 75th Congress’s passage of the FDCA in 1938, and no implication for the plain language of the FDCA’s provisions criminalizing misbranding and adulteration of animal drugs.

As an initial matter, the Supreme Court disfavors reliance on subsequent legislative history in assessing the language and meaning of prior statutes. *See Sullivan v. Finkelstein*, 496 U.S. 617, 628 n.8 (1990) (noting “the usual difficulties inherent in relying on subsequent legislative history”) (citation omitted);²¹ *see also United States v. United Mine Workers of Am.*, 330 U.S. 258, 281-84 (1947) (finding that opinions expressed by Senators were not “authoritative guides to the construction of the Norris-LaGuardia Act” where the opinions were given “eleven years after the Act was passed” by senators, “some of whom were not members of the Senate” when the Act was

¹⁹ In a similar case, albeit one in which the defendant, Darren B. Stratton, pled to an Information charging a § 371 conspiracy pursuant to a plea agreement, the charging instrument specified that the defendant had “defrauded and misled federal and state regulatory agencies, prescription animal drug suppliers, and the general public” by selling prescription animal drugs, including Epogen, without lawful prescriptions. *See* Information, *United States v. Stratton*, No. 18-cr-114 (D.N.H. July 12, 2018) (ECF No. 1).

²⁰ The HISA was passed into law under Title XII, Section 1201 of the Consolidated Appropriations Act, Pub. L. 116-260 (2020).

²¹ *See also Sullivan*, 496 U.S. at 631 (J. Scalia, concurring) (writing that reliance on “subsequent legislative history” is a “contradiction in terms” serving “to smuggle into judicial consideration legislators’ expressions . . . of what a law *previously enacted* means.”).

passed, because the Supreme Court “fail[ed] to see how the remarks of these Senators in 1943 can serve to change the legislative intent of Congress in 1932”). In particular, while “subsequent legislation can of course alter the meaning of an existing law for the future” and “can even alter the past operation of an existing law (constitutional objections aside) *if it makes that retroactive operation clear*,” *Republic of Iraq v. Beatty*, 556 U.S. 848, 862 (2009) (emphasis added) (citing *Landgraf v. USI Film Products*, 511 U.S. 244, 267-68, (1994)), it cannot inferentially amend the purpose behind passage of a prior statute, as defendants wish. To be sure, in certain cases, the Supreme Court has recognized “that the implications of a statute may be altered by the implications of a later statute,” *United States v. Fausto*, 484 U.S. 439, 453 (1988), particularly where a later act requires reconciliation of prior statutes in order for the two to “make sense” in combination. *Id.* “This is particularly so where the scope of the earlier statute is broad but the subsequent statutes more specifically address *the topic at hand*.” *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 143 (2000) (emphasis added). Where no such conflict or need for reconciliation exists, the Supreme Court has expressed consistent skepticism of the interpretation of a statute in light of later acts, noting in response to just such an argument: “All we can know for certain is that speculation about why a later Congress declined to adopt new legislation offers a ‘particularly dangerous basis’ on which to rest an interpretation of an existing law a different and earlier Congress did adopt.” *Bostock v. Clayton Cty., Georgia*, 140 S.Ct. 1731, 1747 (2020) (citing *Pension Benefit Guaranty Corporation v. LTV Corp.*, 496 U.S. 633, 650 (1990); *United States v. Wells*, 519 U.S. 482, 496 (1997); *Finkelstein*, 496 U.S. at 631 (Scalia, J., concurring)); *see also* *Buck v. Sec’y of Health & Human Servs.*, 923 F.2d 1200, 1207 (6th Cir. 1991) (“Subsequent legislative history generally deserves only limited weight.” (citing *United States v. Price*, 361 U.S. 304, 313 (1960), *Consumer Prod. Safety Comm’n v. GTE Sylvania, Inc.*, 447 U.S. 102, 118 n.13

(1980)); *Mackey v. Lanier Collection Agency & Serv., Inc.*, 486 U.S. 825, 840 (1988) (internal quotation marks omitted) (“[T]he views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one.”) (quoting *Price*, 361 U.S. at 313).

The dangers of such *post-hoc* analysis are plain here. Congress did not—in either the FDCA or the HISA—indicate its intent either to acknowledge or create a “racehorse industry” exception to the criminal prohibition against the distribution of adulterated and misbranded drugs with the intent to defraud or mislead in the FDCA, nor did it so indicate with respect to any other federal criminal law. The defendants’ arguments in this respect reflect what seems to be a purposeful misreading of both the HISA and the charges against them: the defendants are not charged with violating state racing anti-doping rules and regulations, for which no federal analogue existed prior to the passage of the HISA; they are charged with felony misbranding and adulteration of drugs in interstate commerce in violation of the FDCA.²² No interpretative gymnastics are required to “make sense” of one statute in light of the other.

The defendants’ position is also in conflict with the text of the HISA. Subsection (k)(3) of Section 1205, regarding the limitations on the newly empowered federal racing authority, states in no uncertain terms: “This Act shall not be construed to modify, impair or restrict the operation of the general laws or regulations . . . of the United States, the States and their political subdivisions

²² Fishman’s motion illustrates the defendants’ arguments on this score. The Fishman Motion argues that “Congress’ assignment of the FTC [Federal Trade Commission] as the agency responsible [under the HISA] . . . and the absence of any criminal provisions in the HISA demonstrates that Congress never intended for the FDA, or any other drug enforcement agency tasked with the performance of similar functions, to regulate or sanction unfair competition in horse racing through the application of the FDCA felony misbranding provisions.” This point is mere misdirection; the charges here do not claim that the FDA imposes criminal liability on the basis of violations of rules relating to “unfair competition.” Rather, the Indictment charges the defendants with violation of the misbranding laws of the United States, committed with an intent to defraud and mislead. *See also* Oakes Mot. at 15 (arguing that the lack of criminal penalties in the HISA evinces Congress’s intent “that Congress did not believe or intend that the FDA or other federal agencies were authorized to regulate the horseracing industry or the use of PEDs in horseracing prior to the Act’s passage.”).

relating to criminal conduct” Notwithstanding the plain language of this provision, defendants nonetheless ask this Court to “modify, impair or restrict” the application of § 333(a)(2), irrespective of the plain language, history, and application of this provision.²³

More likely than the defendants’ contention is a more straightforward explanation: the HISA contains no criminal penalties because Congress determined sufficient criminal penalties were *already* provided for in existing federal criminal laws, laws which the HISA expressly does not modify. Ultimately, though, no reading of the Congressional tea leaves is required. There is no contradiction between the FDCA and the HISA, and no retrospective ambiguity in the text of the former arises from the text of the latter.

f. Even on the Defendants’ Flawed Premise, the Indictment States an Offense

For the reasons set forth above, the defendants’ motions should be denied and, therefore, the Court need not engage with the convenient limitation that the defendants attempt to insert into the language of § 333(a)(2). However, even assuming that § 333(a)(2) did contain the limitation that these defendants propose, the Indictment would nevertheless state a felony offense insofar as it alleges an intent to defraud and mislead multiple parties, *including* federal and state drug regulators, as well as U.S. Customs and Border Protection, various state horse racing regulators, certain horse owners, and the betting public.

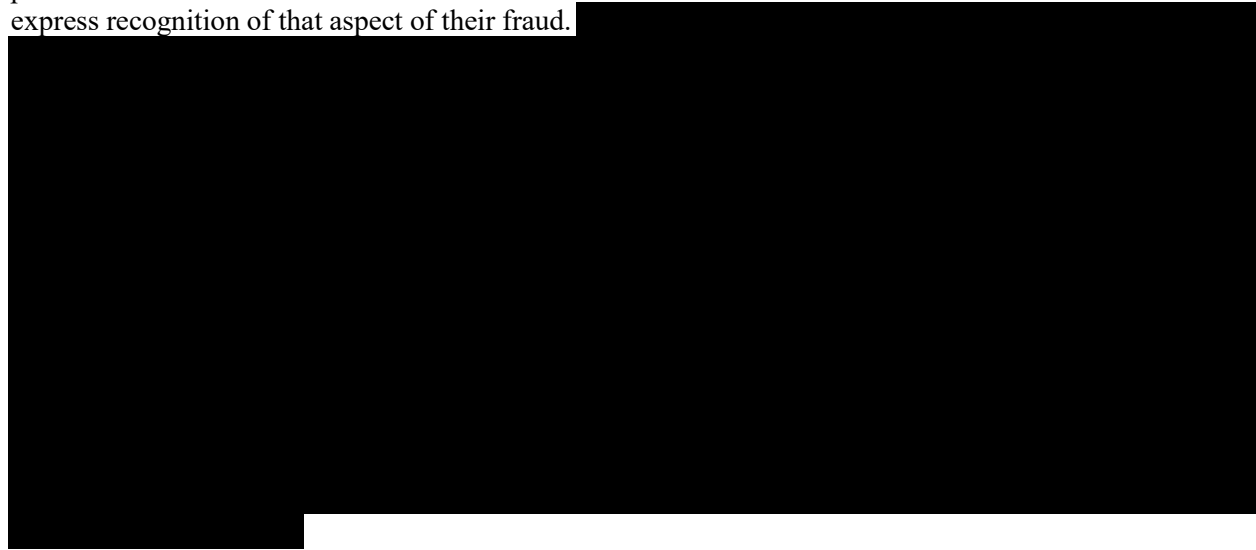
²³ Neither motion grapples with this language in the HISA. The Oakes Motion relies only upon the portion of the HISA that states, “the Commission, the Authority, and the anti-doping and medication control enforcement agency” shall “exercise independent and exclusive national authority” over “the safety, welfare, and integrity of covered horses” and others, “the safety, welfare, and integrity of covered horses” and others, and “all horseracing safety, performance, and anti-doping and medication control matters” (*See* Oakes Mot. at 15). Oakes’ selected language is in fact limited to the exercise of powers “within the scope of [the new federal authority’s] powers and responsibilities,” powers that do *not* include the enforcement of federal criminal laws. Thus, Oakes’ quoted provisions are not intended to limit, much less imply a preexisting limitation of, the application of federal criminal laws over criminals operating in the racehorse industry. This provision is, instead, a limited preemption of the authority of *state* racing commissions to create and enforce a particular subset of racing regulations.

As noted above, the Indictment does allege that the FDA is among the agencies misled and defrauded through the defendants' misbranding offenses. Indictment ¶¶ 3, 15 (incorporating Paragraph 3 into Count One), 30 (incorporating Paragraph 3 into Count Two), 39 (incorporating Paragraph 3 into Count Three).²⁴ The motion fails to that extent even on the defendants' "reading" of § 333(a)(2).

Beyond their recognition of the FDA as a cognizable victim, the two briefs diverge in their efforts to articulate a further limitation. Oakes proposes a specific limitation on § 333(a)(2): "a defendant can only be charged with a felony under the FDCA if the Government alleges that the defendant acted with a specific intent to defraud or mislead a consumer, the FDA, or a government agency *similar to the FDA that is specifically involved in consumer protection*." (Oakes Mot. at 2 (emphasis added)).

Fishman and Giannelli, by contrast, struggle to articulate any particular limitation on the plain language of § 333(a)(2) (apart from their position that the current case cannot possibly fall

²⁴ That the primary federal regulator of misbranded and adulterated drugs would be among the intended victims of the defendants' false labeling and surreptitious distribution methods is readily apparent from the nature of the defendants' schemes. Even were it not, a search for the term "FDA" among the documents produced to the defendants to date results in documents that reflect Seth Fishman and Jordan Fishman's express recognition of that aspect of their fraud.



within its ambit). The closest articulation they provide appears at page 12 of their brief: “if the FDCA contemplated anyone other than consumers as a victim of Section 333(a)(2), that victim must be narrowly construed as the FDA.” Later in their brief, however, they acknowledge that courts have found that “state drug authorities” fall within the scope of the statute (*see* Fishman Mot. at 33, 37-38), and later appear to object to the inclusion of state racing commissions because those agencies are neither state drug authorities nor “concerned with consumer protection.” (Fishman Mot. at 37).²⁵

Taking the defendants’ proposed limitations at face value still results in a felony charge. *First*, the Indictment plainly charges that the defendants intended to defraud, among others also cognizable under § 333(a)(2), “federal and state drug regulators.” *See* Indictment ¶ 3. Second, racing regulators are both drug regulatory agencies and agencies involved in protecting drug consumers (*i.e.*, the animals to whom misbranded or adulterated drugs are administered) as that phrase must be understood in the context of the FDCA.

Racing commissions are agencies that “set[] drug standards, inspect[] drugs, [and] regulate[] the use of prescription drugs.” *Mitcheltree*, 940 F.2d 1352. They are, in short, state agencies directly engaged in drug regulation. The laws creating and empowering these agencies make abundantly clear that these agencies are both committed to the regulation of the use of drugs,

²⁵ Fishman and Giannelli appear committed to the exclusion as victims under § 333(a)(2) of such entities and individuals as: foreign regulators, U.S. Customs officials, suppliers, consignees, pharmacists, drug compounders, or any actors in the supply chain *other* than consumers (and in this respect, only human consumers, notwithstanding the FDCA’s coverage of animal drugs). Being clearer in his proposed limitation, Oakes does not merely *appear* to be committed to the same nonsensical and non-textual exclusion of various market actors and regulators as Fishman and Giannelli; rather, his brief fully embraces that position.

including prescription drugs, and to the protection of the animals to which illicit drugs may administered.²⁶ For example:

- New York. The powers of the New York State Gaming Commission, with respect to the Division of Horse Racing and Pari-Mutuel Wagering’s oversight of thoroughbred racing, include multiple provisions detailing the Commission’s oversight relating to both the health and welfare of the public, including the animals under its supervision, and the use of drugs.²⁷
 - “Furthermore, the commission may refuse to issue or renew a license, or may suspend or revoke a license if, in the opinion of the commission, the refusal to issue or renew a license or the suspension or revocation of a license is *necessary to protect the public health, safety or welfare*.” 9 NYCRR § 4002.9.
 - “(a) No person other than a commission veterinarian, track veterinarian, a practicing veterinarian licensed by the commission, or a veterinary technician who is licensed by the commission and acting with commission approval at the direction and under the supervision of a licensed veterinarian who is on the same premises, is permitted to have or possess in or upon the premises of a licensed or franchised race track, . . . or is permitted to have or possess in his or her personal

²⁶ The defendants’ failure to recognize that the health of animals is a goal of the FDCA – that animals are “consumers” to be protected through the FDCA’s numerous provisions relating to animal drugs – speaks to the defendants’ view of these animals as commodities to be misused and deployed for profit, and not to the actual purpose underlying the FDCA’s regulation of animal drugs. That failure is of a piece with the mistaken view that state racing commissions are solely concerned with “ensur[ing] fair competition in horse racing” and nothing more. (Fishman Mot. at 33).

²⁷ The following provisions relate to the regulation of thoroughbred racing; substantially similar provisions apply to the regulation of harness racing. *See, e.g.*, 9 NYCRR §§ 4120.2 (Restricted use of drugs, medications and other substances), 4120.6 (Possession of hypodermic equipment and controlled substances).

property or effects upon such premises, the following: . . . (2) any controlled substance, listed in schedules I through IV of *section 812 of title 21 of the United States Code (Food and Drugs)* or any drug that has not been approved for use in the horse by the Federal Food and Drug Administration. . . . (d) Each track is required to use all reasonable efforts to prevent and detect violations of this section. . . . (e) A report shall be made to the Bureau of Narcotics of the Department of the Treasury of the United States²⁸ of all cases in which it is reported to the commission that narcotics or other controlled substances have been detected in a specimen from any horse. If any veterinarian or physician has been involved in any such case, a similar report shall be made to the New York State Education Department.”²⁹ 9 NYCRR § 4012.1 (emphasis added).

- “Programs for the detection of the presence of drugs in horses programmed to race shall be conducted at each track unless otherwise ordered by the commission. (a) Pre-Race Testing . . . (3) Blood samples will be taken by the State veterinarian or, under the State veterinarian’s supervision, by a graduate veterinarian. (4) A horse shall not race if it has not been tested in accordance with the provisions of this section.” 9 NYCRR § 4012.3.
- Section 4042.5: “Use of Drugs.” 9 NYCRR § 4042.5.

²⁸ The reference to the “Bureau of Narcotics” is a reference to a predecessor of today’s Drug Enforcement Administration. *See, generally*, The DEA Years, DRUG ENFORCEMENT ADMINISTRATION (2018), *available at* <https://www.dea.gov/sites/default/files/2018-07/1970-1975%20p%2030-39.pdf> (last visited Feb. 24, 2021); *see also* 33 Federal Register 5611 (Reorganization Plan No. 1 of 1968) (Apr. 11, 1968), *available at* <https://tile.loc.gov/storage-services/service/l1/fedreg/fr033/fr033071/fr033071.pdf> (last visited Feb. 24, 2021).

²⁹ The New York State Department of Education, through its Office of the Professions, oversees the practice of veterinary medicine in New York State. *See* NYSED.Org, Office of the Professions, *available at* <http://www.op.nysed.gov/> (last visited Feb. 24, 2021).

- “Drugs and medications are permitted *to be used* only in accordance with the following provisions.” 9 NYCRR § 4043.2 (emphasis added).
- “(a) The substances and methods listed in the ARCI prohibited list are prohibited, *may not be used* at any place or time and may not be possessed on the premises of any racing or training facility under the jurisdiction of the commission except as a restricted therapeutic use.” 9 NYCRR § 4043.12 (emphasis added).
- “(a) No drug may be administered except in the context of a valid veterinarian-client-patient relationship between an attending veterinarian, the horse owner (who may be represented by the trainer or other agent) and the horse.” 9 NYCRR § 4043.16.³⁰
- Florida. The powers of the Florida Division of Pari-Mutuel Wagering, within the Department of Business and Professional Regulation, include the oversight of horseracing in that state and multiple provisions detailing the Division’s oversight relating to both the health and welfare of the public, including the animals under its supervision, and the use of drugs.
 - “(1)(a) The racing of an animal that has been impermissibly medicated or determined to have a prohibited substance present is prohibited. . . . (7)(a) *In order to protect the safety and welfare of racing animals* and the integrity of the races in which the animals participate, the division shall adopt rules establishing the conditions of use and maximum concentrations of medications, drugs, and

³⁰ In addition, the public mission statement of the New York Gaming Commission states that the “Commission’s mission is to ensure that all lawful gaming and horse racing activity . . . is of the highest integrity, credibility, and quality,” to include “*promot[ing] the health and safety of horses* and all participants in racing.” About the New York State Gaming Commission, <https://www.gaming.ny.gov/about/> (last visited March 2, 2021) (emphasis added).

naturally occurring substances identified in the Controlled Therapeutic Medication Schedule, Version 2.1, revised April 17, 2014, adopted by the Association of Racing Commissioners International, Inc. Controlled therapeutic medications include only the specific medications and concentrations allowed in biological samples which have been approved by the Association of Racing Commissioners International, Inc., as controlled therapeutic medications.” Fla. Stat. § 550.2415 (emphasis added).

- “The purpose of these rules related to Medication, Drugs and Sampling is to protect the integrity of horse racing, . . . *to protect the welfare of the animal*, and to safeguard the interest of the public and racing participants *through the control of all medications, drugs, and substances foreign to or in excess of the natural physiology of the animal*.” Fla. Admin. Code § 61D-6.001 (emphasis added).
- “The trainer of record shall be responsible for insuring that all legend drugs, proprietary drugs, or medicinal compounds (natural or synthetic) of any nature are kept or stored at all times in a securely locked cabinet, locker, or room when not actively being administered.” Fla. Admin. Code § 61D-6.003.
- “The administration, by whatever means, of any medication, except furosemide and prednisolone sodium succinate, to a racing animal within 24 hours prior to the officially scheduled time of a race in which that animal is scheduled to compete is strictly prohibited.” Fla. Admin. Code § 61D-6.004.
- “(1) The prescription medications defined in this rule shall be permitted under the conditions set forth to conserve and protect the health of the horse which is entered to race. All such medications shall be procured and administered by a

licensed veterinarian, except where a valid prescription or dispensing occurs in compliance with the requirements of chapter 474, F.S. . . .” Fla. Admin. Code § 61D-6.008.

- “(3) The penalties corresponding to the drug or medication classification, as provided in the incorporated Classification and Penalty Guidelines, shall be imposed when a horse has been impermissibly medicated or determined to have a prohibited substance present in its body in violation of Section 550.2415, F.S.” Fla. Admin. Code § 61D-6.011.
- Pennsylvania. The powers of the Pennsylvania State Horse Racing Commission include the oversight of thoroughbred horseracing in that state and multiple provisions detailing the Commission’s oversight relating to both the health and welfare of the public, including the animals under its supervision, and the use of drugs.
 - “(a) Policy. The purpose of this section . . . is to protect the integrity of horse racing, *to guard the health of the horse* and to safeguard the interests of the public and the racing participants through the prohibition or control of drugs and medications or substances foreign to the natural horse. In this context: (1) A horse participating in a race may not carry in its body a substance foreign to the natural horse except as otherwise provided. (2) A person acting alone or in concert may not administer or cause to be administered a substance to a horse entered to race by injection, oral administration, rectal infusion or suppository, or by inhalation within 24 hours prior to the scheduled post time for the first race, except as otherwise provided. . . .” 58 Pa. Admin. Code § 163.302 (emphasis added).

- “A foreign substance of accepted therapeutic value may be administered as prescribed by a veterinarian when test levels and guidelines for its use have been established by the Veterinary-Chemist Advisory Committee of the National Association of State Racing Commissioners and approved by the Commission.” 58 Pa. Admin. Code § 163.304.
- “A licensee or other person under the jurisdiction of the Commission may not alone or in concert with another person permit an animal under his control to be subjected to a form of cruelty, mistreatment, neglect or abuse or abandon, or to injure, maim or kill or administer a noxious or harmful substance to or deprive an animal of necessary care, sustenance, shelter or veterinary care.” 58 Pa. Admin. Code § 163.317.³¹
- New Jersey. The powers of the New Jersey Racing Commission include the oversight of horseracing in that state and multiple provisions detailing the Commission’s oversight relating to both the health and welfare of the public, including the animals under its supervision, and the use of drugs.
 - “(a) It shall be the intent of these rules to protect the integrity of horse racing, *to guard the health of the horse*, and to safeguard the interests of the public and racing participants through the prohibition and/or control of all drugs and/or substances foreign to the natural horse.” N.J. Admin. Code § 13:70-14A.1 (emphasis added).

³¹ The Pennsylvania State Horse Racing Commission is a division of the Pennsylvania Department of Agriculture, whose publicly stated purpose is to “protect[] human, animal, environmental, and plant health through regulatory oversight,” About PDA, https://www.agriculture.pa.gov/about/about_pda/Pages/default.aspx (last visited March 2, 2021).

- “All drugs, medications, pharmaceutical products and any other substances of a similar nature possessed or used within the grounds of a racing association shall at all times *bear appropriate labelling displaying the contents thereof.*” N.J. Admin. Code § 13:70-27.2 (emphasis added).³²
- Delaware. The powers of the Delaware Thoroughbred Racing Commission include the oversight of thoroughbred horseracing in that state and multiple provisions detailing the Commission’s oversight relating to both the health and welfare of the public, including the animals under its supervision, and the use of drugs.³³
 - “Horses should not compete under the influence of drugs or therapeutic medications. However, horses, in training, like all athletes, may require the administration of therapeutic medications at times to diagnose or treat illness or injury. *Certain drugs have no therapeutic use in horses in training, and these drugs should not be administered to horses in training, nor should they be*

³² The Fishman Motion selectively quotes from the New Jersey Racing Commission’s publicly posted description of its mandate, to exclude references to the Commission’s oversight of drug use. The New Jersey Racing Commission states that it is “responsible for regulating the *safety* and integrity of the horse racing industry through the conduct of investigations, prosecutions, and via regular monitoring.” About the NJ Racing Commission, <https://www.nj.gov/oag/racing/about.html> (last visited March 2, 2021) (emphasis added). The Fishman Motion, however, omitted the following further explanation of the Commission’s role in drug oversight: “It [the Commission] oversees the actual conduct of races, *supervises the extraction of fluid and blood specimens from horses for chemical analysis* and conducts initial hearings on appeals resulting from disciplinary actions that may lead to judicial proceedings at the federal level”; and “[a]s part of the monitoring program *to ensure that no illegal* or banned substances are being used, Commission employees collected blood and urine specimens from horses and urine specimens from jockeys, drivers and officials that are tested for the presence of *illegal substances.*” *Id.* (emphasis added).

³³ In Delaware, the regulation of harness racing is conducted by the Harness Racing Commission pursuant to laws and regulations similar to those applicable to thoroughbred contests. *See generally*, 3 Del. Admin Code § 501; *see also* 3 Del. Admin Code § 501-8.1 (“The purpose of this Rule [‘Veterinary Practices, Equine Health Medication’] is to protect the integrity of horse racing, *to ensure the health and welfare of race horses* and to safeguard the interests of the public and the participants in racing.”); *id.* § 501-8.7.1.2 (prohibiting “The possession and/or use of a drug, substance, or medication that has not been approved by the United States Food and Drug Administration (FDA) for use in the United States”).

permitted at any concentration in post-race samples.” 3 Del. Admin. Code. § 1001.15.1.1 (emphasis added).

- “The following conduct shall be prohibited for all licensees: . . . 15.12.1.2: The possession and/or use of a drug, substance, or medication on the premises of a facility under the jurisdiction of the regulatory body that *has not been approved by the United States Food and Drug Administration (FDA) for use in the United States.*” 3 Del. Admin. Code. § 1001.15.12.1 (emphasis added).³⁴

These five states’ racing regulators, each misled and defrauded by at least certain of the defendants in this case, are not unusual in either their missions or methods. Such agencies, nationwide, ensure the safety of horses (the “consumers” of animal drugs) and “set[] drug standards, inspect[] drugs, [and] regulate[] the use of prescription [and other] drugs.” *Mitcheltree*, 940 F.2d 1352. As noted above, certain states make express reference to non-FDA-approved drugs and specifically regulate the content and labeling of drugs allowed onto racetrack premises. Repeatedly, states expressly describe the mission of their racing commissions as protecting the health and safety of the animals participating in contests in those states— unsurprising given the danger to the health and welfare of horses inherent in the illicit administration of medically unnecessary or shoddily manufactured drugs.

³⁴ The publicly posted mission statement of the Delaware Thoroughbred Racing Commission includes “eliminat[ing] fraudulent activity that would undermine the public trust . . . [and] preventing and eliminating corrupt practices.” Thoroughbred Racing Commission: Mission, <https://agriculture.delaware.gov/thoroughbred-racing-commission/> (last visited March 2, 2021). The Delaware Harness Racing Commission also publicly states, “The key objective of the Commission is to maintain hands-on supervision of all investigative cases involving evidence of race-fixing, horse substitution, *illegal medication* . . . and others.” Delaware Harness Racing Commission, <https://agriculture.delaware.gov/harness-racing-commission/> (last visited March 2, 2021) (emphasis added).

In the course of these defendants’ offense, and indeed as a necessary feature of *completing* certain aspects of these defendants’ charged offenses, the defendants sought to defraud and mislead racing regulators and racetracks, among other victims identified in the Indictment, such as state drug regulators. That is, they committed their misbranding offenses “with the intent to defraud or mislead.” Certain of the defendants’ victims are identified in the Indictment as state drug regulators, and that allegation is proper under the plain language of § 333(a)(2), the case law interpreting that provision, and even under the defendants’ self-serving amendment thereto.

g. Tannuzzo’s Motion to Dismiss Should Be Denied

Tannuzzo’s motion distils to a singular grievance that Count One of the Indictment is deficient because it fails to detail the entirety of the Government’s evidence against Tannuzzo. In pressing that argument, Tannuzzo largely strays from a motion to dismiss pursuant to Rule 12 into argument for a judgment of acquittal based on Rule 29, notwithstanding that there has been no trial and, thus, the Government has not “close[d] its evidence.” *Compare* Fed. R. Crim. Pro. 29(a) *with* Tannuzzo Mot. at 1 (“This motion is made pursuant to the Federal Rules of Procedure . . . 29(a)”); *id.* at 19-21 (explicitly citing and discussing the Rule 29 standard for judgment of acquittal). Perhaps because of that confused posture, Tannuzzo’s motion is replete with arguments regarding the perceived insufficiency of the Government’s evidence against Tannuzzo generally, rather than those regarding the allegations in the Indictment. *See, e.g.*, Tannuzzo Mot. at 12 (“[T]here was no agreement to engage in criminal activity between Mr. Tannuzzo and Jorge Navarro under these facts as presented to the Grand Jury”);³⁵ *id.* at 16 (“[T]here was no meeting of the minds between

³⁵ Many of Tannuzzo’s arguments presuppose that certain evidence was or was not presented to the grand jury that returned the Indictment. *See, e.g.*, Tannuzzo Mot. at 15 (“[T]he Government submitted to the Grand Jury speculative and assumptive claims with regard to” Tannuzzo); *id.* at 20 (“[I]t is not enough for the Government to then reply in their papers that they have evidence supporting the accusation when that evidence was not presented to the Grand Jury and no further acts were claimed, and Mr. Tannuzzo was not

Jorge Navarro and Mr. Tannuzzo to receive, deliver, and administer PEDs to racehorses Equally prejudicial is the fact that the claim as applied only to Mr. Tannuzzo makes a considerable leap to suggest a meeting of the minds”).

Tannuzzo hardly engages on the operative legal standard, which is fatal to his motion to dismiss: an Indictment need “do little more than to track the language of the statute charged and state the time and place (in approximate terms) of the alleged crime.” Order Dismissing S. Fishman Mot. for Bill of Particulars at 15 (ECF No. 244) (quoting *United States v. Bout*, 731 F.3d 233, 240 (2d Cir. 2013)). The Indictment meets that standard.

Having met that standard through the basic statutory allegations, the Indictment provides additional details regarding the nature of the conspiracy, the identity of Tannuzzo’s coconspirators, the identity of particular drugs relevant to their conspiracy, and details of particular acts taken in furtherance of the conspiracy by Tannuzzo and others. Tannuzzo’s arguments claiming that still more details are required—predicated in part on case law from the 1800s, before the Federal Rules of Criminal Procedure were adopted, *see* Tannuzzo Mot. at 10, are simply incorrect, *see Bout*, 731 F.3d at 240, and do not accord with Rule 7’s requirement that an indictment contain “a plain, concise, and definite written statement of the essential facts,” FED. R. CRIM. P. 7(c)(1).

Much of Tannuzzo’s complaint centers around various arguments about the sufficiency and accuracy of the overt act alleged at Paragraph 29(g) of the Indictment. Tannuzzo’s argument

indicted for those further and additional acts.”). There is no foundation for these arguments given that Tannuzzo does not know the substance of the presentation to the grand jury. Nor is it relevant; in adjudging a motion to dismiss, the Court need only look to the text of the indictment itself, and the Court must accord a presumption of regularity to the grand jury proceedings that led to the return of the Indictment. *See Hamling v. United States*, 418 U.S. 87, 139 n.23, (1974) (agreeing with the Circuit Court that “[t]he presumption of regularity which attaches to Grand Jury proceedings still abides”); *United States v. McSherry*, 229 F.3d 1136 (2d Cir. 2000) (citing *United States v. Ferrara*, 990 F.Supp. 146, 152 (E.D.N.Y. 1998) for the proposition that there is a “strong presumption of regularity in grand jury proceedings” which “cannot be outweighed by purely conclusory or speculative allegations.”).

fails to account for the fact that the Indictment does not itemize the totality of the Government's evidence, nor need it do so. *Compare* Tannuzzo Mot. at 13 ("It is not enough for the Government to tell the Court that 'we have other evidence' and not have disclosed that evidence in the Indictment to Mr. Tannuzzo"); *id.* at 15 ("I anticipate that the Government will then claim that other evidence supports this claim, meanwhile none of those purported acts are included in the undetailed Indictment against Mr. Tannuzzo"), *with Bout*, 731 F.3d at 240.³⁶ The argument simultaneously claims that Tannuzzo cannot understand the evidence against him in light of purportedly limited allegations in the Indictment, draws on the Government's easily searchable evidence produced in discovery, and then selectively quotes from that evidence in a manner designed to mislead the reader as to the facts surrounding the overt act naming Tannuzzo alleged in the Indictment.

Specifically, Tannuzzo asserts that the "May 15, 2019 telephone call between Jorge Navarro and Mr. Tannuzzo" referenced in Paragraph 29(g) of the Indictment does not establish the

³⁶ Tannuzzo specifically does *not* request a bill of particulars. *See* Tannuzzo Mot. at 10 ("Our courts have held that a Bill of Particulars cannot save an invalid indictment"). Were he to do so, that request would be meritless for the same reasons set forth in the Court's Opinion as to Seth Fishman's prior motion. *See also* *United States v. Cephas*, 937 F.2d 816, 823 (2d Cir. 1991) (the Government is not required to "particularize all its evidence"); *United States v. Mitlof*, 165 F. Supp. 2d 558, 569 (S.D.N.Y. 2001) (The "'wheres, whens and with whoms'" are "beyond the scope of a bill of particulars." (citing *United States v. Torres*, 901 F.2d 205, 233-34 (2d Cir. 1990)); *United States v. Persico*, 621 F. Supp. 842, 868 (S.D.N.Y. 1985) ("Details as to how and when the conspiracy was formed, or when each participant entered it, need not be revealed before trial."); *United States v. Levy*, No. S5 11 CR. 62 (PAC), 2013 WL 664712, at *4, 13 (S.D.N.Y. Feb. 25, 2013), *aff'd*, 803 F.3d 120 (2d Cir. 2015) (in case charging stock manipulation through false representations by corrupt brokers, request for bill of particulars recounting "each specific misrepresentation and omission alleged" denied as "simply a request to compel the production of the very type of evidentiary minutiae that is not appropriate in a bill of particulars") (citation and quotation marks omitted); *United States v. Guttenberg*, No. 07 Cr. 141 (DAB), 2007 WL 4115810, at *4-5 (S.D.N.Y. 2007) (in insider trading case, denying request for bill of particulars itemizing trades alleged to have been based on material nonpublic information); *United States v. Bortnick*, No. 03 Cr. 414 (JD), 2005 WL 1693924, at *21 (E.D. Pa. July 20, 2005) ("Courts have consistently held that, in fraud cases, the government is not required to prove every allegation of fraudulent activity that appears in the indictment. The government must prove a sufficient number of fraudulent activities to support a jury inference that there was an overall fraudulent scheme.") (citing *United States v. Amrep Corp.*, 560 F.2d 539, 546 (2d Cir. 1977)).

elements of a conspiracy, and thereby renders the Indictment deficient based on evidence extrinsic to the Indictment. *See* Tannuzzo Mot. at 13. In particular, Tannuzzo alleges that this overt act “fails to establish Mr. Tannuzzo’s knowledge that the package he was dropping off was in fact adulterated and misbranded PEDs, but also that he had a specific intent to mislead or defraud regulatory officials.” *Id.* at 18. Of course, no particular overt act is required, in itself, to repeat the statutory allegations set forth in the paragraphs immediately preceding it, nor is a single conspiratorial act required in itself to encapsulate every element of a charged offense. *United States v. Montour*, 944 F.2d 1019, 1026 (2d Cir. 1991) (“[A]n overt act need not be inherently criminal to support a conspiracy conviction.”); *see also Braverman v. United States*, 317 U.S. 49, 53 (1942) (“The overt act, without proof of which a charge of conspiracy cannot be submitted to the jury, may be that of only a single one of the conspirators and need not be itself a crime.”).

As to the accuracy of the allegation, and specifically as to the inferences that a jury might one day draw as to the Government’s evidence, Tannuzzo’s argument is plainly premature. *See* Fed. R. Crim. Pro. 29(a). It is also profoundly misleading. While claiming that “Tannuzzo’s guilt is hiding . . . in terabytes of discovery,” Tannuzzo Mot. at 13, Tannuzzo has plainly managed to locate and selectively quote from the intercepted communications between himself and Navarro that make plain the import of the overt act alleged at Paragraph 29(g).³⁷ Far from picking up a

³⁷ The Government has provided counsel with easily-searchable linesheets containing summaries and in some cases draft transcriptions of recorded calls, and text message contents of approximately 2,150 intercepted communications between Navarro and Tannuzzo between in or about January 2019 and in or about June 2019 (and the call recordings themselves). Indeed, Tannuzzo has had access to a telephone seized from co-conspirator Ross Cohen since it was produced to defense counsel in or about July 2020, and the Government has even highlighted for defense counsel certain text messages between Cohen and Tannuzzo extracted from this device image, in which Tannuzzo confirms multiple times his purchase and receipt of the blood builder “Monkey.”

The suggestion that Tannuzzo has not, or cannot, identify relevant evidence in the Government’s productions is unfounded.

package of legal “medication” for his friend Navarro, Tannuzzo and Navarro communicated extensively about the shipment and receipt, not of anodyne “medication,” but of misbranded and adulterated PEDs:

- [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
- | [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
- | [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
- | [REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Though he has no obligation to do so, Tannuzzo will be welcome to claim to a jury that his interactions with Navarro, as reflected in Paragraph 29(g), and with others involved in the charged offense were entirely unobjectionable, but that claim is both premature and false.

CONCLUSION

For the reasons set forth above, the Government respectfully requests that the Court deny the motions in their entirety.

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Respectfully submitted,

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